

# United States of America/Pharmaceuticals, Biotechnology & Life Sciences 16 April 2017

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# **Baricitinib Disappointment**

What's new? Complete Response Letter for baricitinib

Following a 3-month review extension from the original January 2017 PDUFA for the FDA to review additional data analyses, the FDA issued a Complete Response Letter (CRL) for baricitinib for treating rheumatoid arthritis. According to Lilly's press release, the FDA is unable to approve the application in its current form, and specifically the agency would like (1) additional clinical data to determine the most appropriate doses and (2) additional data to further characterize safety concerns across treatment arms. Despite this setback, Lilly reaffirmed its financial guidance for 2017 and its mid-term guidance for the remainder of this decade. Our takeaway: Baricitinib in RA could be delayed a few years

The CRL is clearly negative news for Lilly and its partner Incyte. The requests by the FDA for additional clinical data to determine the "most appropriate" doses and safety data suggest that Lilly may need to conduct at least another clinical study to gather the data, and if this is the case, it could take a few years to complete and will probably push out commercialization of baricitinib in RA. However, both Lilly and its partner Incyte disagree with the FDA's conclusions and expect to have further discussions with the FDA, and so the timing could be earlier if they're successful in their discussions with the FDA. It looks like the programs in other indications will continue, such as the phase 2 trials for atopic dermatitis and systemic lupus erythematosus, and a phase 3 trial for patients with psoriatic arthritis is still on track to start in 2017. We note that the FDA's decision is at odds with the EU approval of baricitinib (Olumiant). We currently have risk- adj sales of \$55M and \$230M for 2017 and 2018, which translate to an EPS of \$0.02 and ~\$0.10, respectively.

Thoughts on the stock: Likely to be down some

We believe an FDA approval of baricitinib in RA was highly expected given the positive February EU decision, and the positive efficacy and safety data from the four Phase 3 studies that have been presented, which until now have not raised serious concerns. So, we think the CRL will likely come as a surprise to the Street. The disappointing baricitinib news should be a positive for Pfizer's Xeljanz, as competition is delayed.

Valuation: Maintaining our Neutral rating and price target of \$85 Our price target is based on a P/E of ~19x our 2018 EPS of \$4.45.

12-month rating	Neutral
12-month price target	\$85.00
Price	\$85.88

Contributing authors: Uy Ear

Trading data and key metrics			
52-wk range	US\$86.25-65.97		
Market cap.	US\$91.2bn		
Shares o/s	1,061m (COM)		
Free float	100%		
Avg. daily volume ('000)	1,091		
Avg. daily value (m)	US\$88.3		
Common s/h equity (12/17E)	US\$14.6bn		
P/BV (12/17E)	6.2x		
Net debt / EBITDA (12/17E)	1.3x		
RIC	LLY.N		
BBG	LLY US		

Sources: UBS, Bloomberg

EPS (UBS, diluted) (US\$)			
-	12/17E		
	UBS	Cons.	
Q1E	0.97	0.96	
Q2E	1.03	1.03	
Q3E	1.05	1.05	
Q4E	1.10	1.07	
12/17E	4.15	4.11	
12/18E	4.45	4.41	
12/19E	4.95	5.05	

# Performance Stock Price (USD) 100 — 90 —



Sources: Bloomberg, UBS

Definitions of terms and abbreviations are available in the appendix section of this report, and more extensively on internet at  $\frac{1}{2} \frac{1}{2} \frac{1$ 

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#### Company Profile: Lilly (Eli) & Co.

Eli Lilly & Co., with its subsidiaries, develops, makes and markets pharmaceutical and animal health products, sold in approximately 155 countries around the world. Key franchises include central nervous system and endocrine disorders, oncology and women's health.

#### **Statement of Risk**

Our price target is based on a P/E multiple. Lilly faces several risks impacting the overall pharmaceutical industry including (1) pricing pressure and branded drug restrictions resulting from healthcare reform or managed care initiatives; (2) generic competition as well as competition from other international branded players; (3) clinical and regulatory risk with regard to new product development; (4) inability to develop or acquire suitable pipeline assets; and (5) political instability risk associated with multi-national operations.

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Highlights (US\$m)	12/14	12/15	12/16	12/17E	12/18E	12/19E	12/20E	12/21E
Revenues	19,615	19,958	21,219	22,068	22,016	22,581	23,637	24,606
EBIT (UBS)	3,978	4,359	4,552	5,557	5,950	6,396	6,817	7,113
Net earnings (UBS)	3,336	3,644	3,733	4,402	4,719	5,096	5,392	5,599
EPS (UBS, diluted) (US\$)	3.11	3.42	3.52	4.15	4.45	4.95	5.40	5.77
DPS (US\$)	1.96	2.00	2.04	2.12	2.16	2.21	2.25	2.25
Net (debt) / cash	(7,596.50)	(6,299.50)	(9,117.60)	(8,315.76)	(7,667.10)	(8,835.18)	(10,251.43	) (11,471.77)
Profitability/valuation	12/14	12/15	12/16	12/17E	12/18E	12/19E	12/20E	12/21E
EBIT margin %	20.3	21.8	21.5	25.2	27.0	28.3	28.8	28.9
ROIC (EBIT) %	28.4	28.7	25.5	30.2	31.5	32.4	33.5	33.9
EV/EBITDA (core) x	14.1	16.8	15.1	14.4	13.5	12.6	11.9	11.4
P/E (UBS, diluted) x	19.8	23.0	21.7	20.7	19.3	17.3	15.9	14.9
Equity FCF (UBS) yield %	5.2	2.0	4.8	3.8	5.1	5.3	5.5	5.7
Net dividend yield %	3.2	2.5	2.7	2.5	2.5	2.6	2.6	2.6

Source: Company accounts, Thomson Reuters, UBS estimates. Metrics marked as (UBS) have had analyst adjustments applied. Valuations: based on an average share price that year, (E): based on a share price of US\$85.88 on 13 Apr 2017 19:33 EDT

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UBS 12-Month Rating	Rating Category	Coverage <sup>1</sup>	IB Services <sup>2</sup>
Buy	Buy	45%	29%
Neutral	Hold/Neutral	39%	27%
Sell	Sell	15%	16%

<sup>1:</sup>Percentage of companies under coverage globally within the 12-month rating category.

Source: UBS. Rating allocations are as of 31 December 2016.

UBS 12-Month Rating	Definition
Buy	FSR is > 6% above the MRA.
Neutral	FSR is between -6% and 6% of the MRA.
Sell	FSR is > 6% below the MRA.

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#### **Global Equity 12-Month Rating Definitions**

Buy: FSR is > 6% above the MRA. Neutral: FSR is between -6% and 6% of the MRA. Sell: FSR is > 6% below the MRA.

#### **Key Definitions**

**Forecast Stock Return (FSR)** is defined as expected percentage price appreciation plus gross dividend yield over the next 12 months. **Market Return Assumption (MRA)** is defined as the one-year local market interest rate plus 5% (a proxy for, and not a forecast of, the equity risk premium).

**Under Review (UR)** Stocks may be flagged as UR by the analyst, indicating that the stock's price target and/or rating are subject to possible change in the near term, usually in response to an event that may affect the investment case or valuation.

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#### **Company Disclosures**

Company Name	Reuters	12-mo rating	Price	Price date
Lilly	LLY US	Neutral	US\$85.88	13 Apr 2017

Source: UBS. All prices as of local market close.

Ratings in this table are the most current published ratings prior to this report. They may be more recent than the stock pricing date

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Source: UBS CIO as of 16 April 2017

Terms and Abbrevi			
Term / Abbreviation	Description / Definition	Term / Abbreviation	Description / Definition
1H, 2H, etc. or 1H11,	First half, second half, etc. or first half 2011,		First quarter, second quarter, etc. or first quarter
2H11, etc.	second half 2011, etc.	2Q11, etc.	2011, second quarter 2011, etc.
2011E, 2012E, etc.	2011 estimate, 2012 estimate, etc.	A	actual i.e. 2010A
ADR	American depositary receipt	ARPU	Average Revenue Per User
AUM	Assets under management = total value of own and third-party assets managed	Avg.	average
bn	Billion	bp or bps	Basis point or basis points (100 bps = 1 percentage point)
BVPS	Book value per share = shareholders' equity divided by the number of shares	CAGR	Compound annual growth rate
Cant Inc/Capita	Cantonal income per capita (Switzerland only)	Capex	Capital expenditures
CF	Cash flow	CFO	1) Cash flow from operations, 2) Chief financia officer
COGS	Cost of goods sold	COM	Common shares
Cons.	Consensus	Core Tier 1 Ratio	Tier 1 capital minus tier 1 hybrid securities
Cost/Inc Ratio (%)	Costs as a percentage of income	CPI	Consumer price index
CR	Combined ratio = ratio of claims and expenses as a percentage of premiums (for insurance companies)	CY	Calendar year
DCF	Discounted cash flow	DDM	Dividend discount model
Dividend Yield (%)	Dividend per share divided by price per share	DPS	Dividend per share
E	expected i.e. 2011E	EBIT	Earnings before interest and taxes
EBIT Margin (%)	EBIT divided by revenues	EBITDA	Earnings before interest, taxes, depreciation and amortization
EBITDA Margin (%)	EBITDA divided by revenues	EBITDA/Net Interest	EBITDA divided by net interest expense
EBITDAR	Earnings before interest, taxes, depreciation, amortization and rental expense	EFVR	Estimated fair value range
EmV	Embedded value = net asset value + present value of forecasted future profits (for life insurers)	EPS	Earnings per share
Equity Ratio (%)	Shareholders' equity divided by total assets	EV	Enterprise value = market value of equity, preferred equity, outstanding net debt and minorities
FCF	Free cash flow = cash a company generates above outlays required to maintain/expand its asset base	FCF Yield (%)	Free cash flow divided by market capitalization
FFO	Funds from operations	FY	Fiscal year / financial year
GDP	Gross domestic product	Gross Margin (%)	Gross profit divided by revenues
Н	half year	h/h	Half-year over half-year; half on half
hist av.	Historical average	Interbank Ratio	Interbank deposits due from banks divided by interbank deposits due to banks
Interest Coverage	Ratio that expresses the number of times interest expenses are covered by earnings	Interest exp	Interest expense
ISIN	International securities identification number	K	One thousand
LLP/Net Int Inc (%)	Loan loss provisions divided by net interest income	LLR/Gross Loans (%)	Loan loss reserves divided by gross loans

Term / Abbreviation	Description / Definition	Term / Abbreviation	Description / Definition
LPR	Least Preferred: The stock is expected to both underperform the relevant benchmark and	Market cap	Number of all shares of a company (at the end of the quarter) times closing price
	depreciate in absolute terms.		2
m/m	Month-over-month; month on month	mn or m	Million
M and A	Merger and Acquisition	MP	Marketperform: The stocks expected performance is in line with the sector benchmark
MPR	Most Preferred: The stock is expected to both outperform the relevant benchmark and appreciate in absolute terms.	n.a.	Not available or not applicable
NAV	Net asset value	Net Debt	Short- and long-term interest-bearing debt minus cash and cash equivalents
Net DPS	Net dividends per share	NIM or Net Int Margin (%)	Net interest income divided by average interest- bearing assets
Net Margin (%)	Net income dividend by revenues	NV	Neutral View: The stock is expected to neither outperform nor underperform the relevant benchmark nor significantly appreciate or depreciate in absolute terms.
n.m. or NM	Not meaningful	NPL	Non-performing loans
OP	Outperform: The stocks is expected to outperform the sector benchmark	Op Margin (%)	Operating income divided by revenues
p.a.	Per annum (per year)	P/BV	Price to book value
P/E or PE	Price to earnings / Price Earnings Ratio	P/E Relative	P/E relative to the market
P/EmV	Price to embedded value	PEG Ratio	P/E ratio divided by earnings growth
PPI	Producer price index	Prim Bal/Cur Rev (%)	Primary balance divided by current revenue (total revenue minus capital revenue)
Profit Margin (%)	Net income divided by revenues	q/q or QQQ	Quarter-over-quarter; quarter on quarter
R and D	Research and development	ROA (%)	Return on assets
ROAE (%)	Return on average equity	ROCE (%)	Return on capital employed = EBIT divided by difference between total assets & current liabilities
ROE (%)	Return on equity	ROIC (%) or ROI	Return on invested capital
Shares o/s	Shares outstanding	Solvency Ratio (%)	Ratio of shareholders' equity to net premiums written (for insurance companies)
sotp or SOTP	Sum of the parts	Tax Burden Index	Swiss tax index; 100 = average tax burden of all cantons
tgt	Target	Tier 1 Ratio (%)	Tier 1 capital divided by risk-weighted assets; describes a bank's capital adequacy
tn	Trillion	UP	Underperform: The stock is expected to underperform the sector benchmark
Valor	Swiss company identifier	WACC	Weighted average cost of capital
CIO	UBS WM Chief Investment Office	Х	multiple / multiplicator
y/y or YOY	Year-over-year; year on year	yr	Year
YTD	Year-to-date		

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